

### **REMARKS/ARGUMENTS**

The office action of September 8, 2004 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Claims 1-12 and 14-33 are pending. Claims 1-12 and 14-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 4,604,089 to Santangelo *et al.* ("Santangelo") in view of U.S. Pat. No. 4,447,224 to DeCant, Jr. *et al.* ("DeCant"). In addition, the specification and the drawings were objected to for failing to provide proper antecedent basis for the claimed subject matter, specifically the terms "flow limiter" and "passive flow rate control element."

In response, the specification and two of the claims have been amended to clarify the subject matter being claimed. The Applicants respectfully traverse the rejection with the following remarks.

#### **Amendment to the Specification**

The specification has been amended to provide additional guidance as to the meaning of the phrase "flow rate control element" pursuant to MPEP 608.01(o). The applicants respectfully submit that the phrase, however, does not invoke 35 U.S.C. § 112, ¶ 6.

#### **Use of Means-Plus-Function Language**

The Office Action objected to the use of means-plus-function language such as found in claims 19 and 26. The Applicants submit that exemplary structure can be found at least in Figure 1, items 16 and 50. Accordingly, such claims are believed to be in a proper format.

#### **Amendment to the Claims**

Claims 15 and 22 were amended to recite a "flow restrictor" rather than a "flow limiter." While it is respectfully asserted that the use of the term "flow limiter" was not improper, to expedite prosecution of the application the term "restrictor" has been used. It is respectfully submitted that the term "restrictor" is supported by the specification and has structural

connotation to one of ordinary skill in the art. Accordingly, it is believed that the reasons for objecting to claims 15 and 22 have been obviated.

**Amendments to the Drawings**

It is respectfully submitted that the amendments to the specification and the claims, as discussed above, obviates the need to amend the drawings. Accordingly, confirmation of acceptability of the drawings is respectfully requested.

**Rejection under 35 U.S.C § 103(a) – Santangelo & DeCant**

Independent claims 1, 6, 11, 14 and 21 were rejected under 35 U.S.C § 103(a) as being unpatentable over Santangelo in view of DeCant.

As an initial matter, the Applicants respectfully disagree with the Office Action's characterization of micro-machined bi-stable valves. For instance, it is respectfully submitted that micro-machined bi-stable valves cannot fairly be considered any valve that opens or closes. The Examiner is invited to review U.S. Patent No. 5,839,467, which is incorporated by reference in the present application.

Turning next to the references recited in the Office Action, Santangelo is directed towards an external pumping system for directing a fluid, such as saline, to a human joint. Figure 1 of Santangelo is provided below:



The system includes a pump 26 that pumps saline from a reservoir 14. (Santangelo, C. 3, L. 35-39). The fluid is directed via a catheter 30 into a joint 12 (such as a human knee). (Santangelo, C. 3, L. 54-57). A second catheter 32 provides an egress for the saline fluid being pumped into the joint so that unwanted pressure does not build up in the joint 12. (Santangelo, C. 3, L. 63-64). Both catheters are sealed to the joint so that the pressure in catheter 30 causes the fluid that enters the joint to exit through the second catheter 32. (Santangelo, C. 3, L. 58-60). The saline fluid returning from the joint 12 via conduit 42 is directed through a normally open valve 56 and a regulator 60. (Santangelo, C. 4, L. 1-29). The saline then returns back to the pump 26 via conduits 78 and 22. (Santangelo, C. 4, L. 1-49). By use of the regulator 60, the pressure of the saline being delivered to the joint is increased. (Santangelo, C. 4, L. 57 – C. 5, L. 2)

Thus, the system of Santangelo provides a method of increasing the pressure of the saline being delivered to the joint 12. In other words, Santangelo does not control the flow of fluid to the delivery site but instead controls the pressure of the fluid being delivered by affecting the flow of fluid away from the delivery site. However, Santangelo does not teach or suggest a

system or method of delivering a bolus to the joint that is parallel with the normal delivery system. Instead, the pump 26 provides a relatively constant flow rate of saline to the joint 12. (Santangelo, C. 3, L. 42-44).

DeCant is directed towards an implantable flow infusion apparatus. Figure 1 of DeCant is provided below.

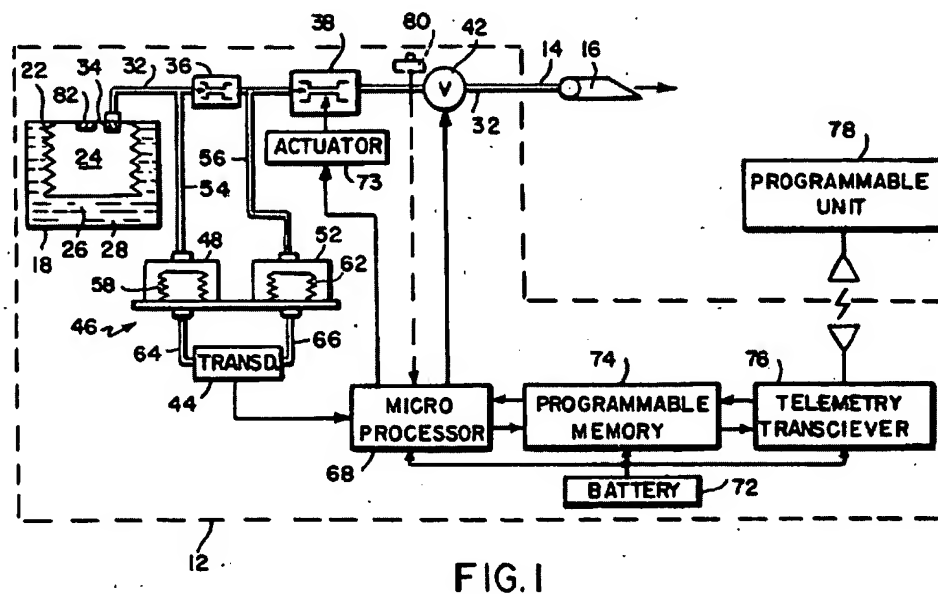


FIG. 1

As is apparent from Figure 1, fluid in chamber 24 is under constant pressure due to a two-phase liquid 28 that vaporizes at physiological temperatures. (DeCant, C. 5, L. 43-50). The fluid in chamber 24 is expelled out through outlet 32 through fixed restrictor 36 and through variable flow restrictor 38, both connected in series to catheter 16. (DeCant, C. 5, L. 52-61). By measuring the pressure drop across fixed restrictor 36, the microprocessor 68 can determine the flow rate and adjust variable flow restrictor 38 accordingly via actuator 73, which is a stepper motor. (DeCant, C. 6, L. 1-27). To ensure the flow rate is correct, the pressure drop across fixed restrictor 36 is regularly checked and adjustments to variable flow restrictor 38 are made as needed. (DeCant, C. 6, L. 43-56). Notably, there is no parallel path for delivering a bolus.

Turning now to independent claim 1, the Office Action rejected claim 1 under 35 U.S.C. §103 in light of Santangelo in view of DeCant. Claim 1 recites the limitation of “the bolus delivery component in parallel communication with the valve.” As noted above, Santangelo does not provide a “bolus delivery component in parallel communication with the valve,” as

recited in claim 1 for instance, rather Santangelo uses an accumulator to increase the pressure of saline being delivered to a joint. Thus, Santangelo fails to disclose at least one limitation of claim 1. Likewise, DeCant also fails to disclose a "bolus delivery component in parallel communication with the valve," as recited in claim 1, for instance, thus the combination of DeCant and Santangelo does not overcome this deficiency.

Furthermore, Santangelo works by sealing supply catheter 30 and egress catheter 32 to the joint so the pressure of the saline being delivered to the joint can be raised. (Santangelo, C. 3, L. 58-60). Santangelo explains that it may desirable to add additional sealing elements around the joint 12 so that a higher pressure may be sustained within the joint. (Santangelo, C. 3, L. 60-63). Such an arrangement, however, would be completely unsuitable for adaptation in an implanted system. Indeed, the Applicants submit that attempting to use such the method of Santangelo in an implanted system would be highly unsafe to the patient. Thus, as the system of Santangelo could not be use in an implanted system, there would be no motivation to combine Santangelo with the implanted system of DeCant, nor would there be any expectation of success.

Accordingly, it is respectfully submitted that the combination of Santangelo and DeCant cannot be fairly said to make claim 1 obvious.

Independent claims 6, 11, 14, 21 all recited a limitation similar to claim 1, thus the combination of Santangelo and DeCant cannot fairly be said to make claims 6, 11, 14 or 21 obvious.

All other claims depend from the above independent claims, thus the combination of Santangelo and DeCant cannot fairly be said to make any of the pending claim obvious.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

### **CONCLUSION**

It is believed that all claims are in allowable condition and that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.


All rejections and objections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

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Respectfully submitted,  
BANNER & WITCOFF, LTD.

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